UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff,

Civil Action No. 3:17-01362

AMERISOUCEBERGEN DRUG CORPORATION, et al. Defendants

CABELL COUNTY COMMISSION, Plaintiff,

v.

v.

AMERISOUCEBERGEN DRUG CORPORATION, et al. Defendants

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF ANDREW KOLODNY

October 23, 2020

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INTRODUCTION

This is one of three motions in which Defendants ask the Court to exclude Dr. Kolodny's expert testimony.¹ What causes Defendants to fight so hard over Dr. Kolodny is exactly what makes his opinions relevant, reliable, and helpful—namely, his deep, recognized, and multi-disciplinary expertise in the origins, nature, and consequences of the Opioid Epidemic.

Dr. Kolodny has worked in, studied, and written, spoken, and testified about the Opioid Epidemic for more than seventeen years. Doc. 1097-27² (Curriculum Vitae attached as Schedule 1 to Dr. Kolodny's Expert Report). His expertise arises not only from his role as a board-certified physician in Addiction Medicine, Psychiatry & Neurology, but also from his roles as a public health official, researcher, and policy advocate. His research and publications on the Opioid Epidemic are extensive and cover such topics as: (1) the role of the opioid industry in promoting opioids, (2) the role and effects of government regulation, and (3) the impact of financial conflicts of interest.³ Dr. Kolodny's expertise in the Opioid Epidemic has been recognized by a multitude

¹ In addition to this motion seeking to exclude Dr. Kolodny's testimony on five alleged grounds, Defendants have sought to exclude portions of Dr. Kolodny's testimony in their Motion to Exclude the Marketing Opinions of Anna Lembke, Katherine Keyes, Andrew Kolodny, and Jakki Mohr [ECF 1063-1064] and in their Motion to Exclude Expert Testimony Concerning Defendants' Corporate Conduct [ECF 1043-1044].

² ECF Doc. No. 1097 is Plaintiffs' Appendix of Expert Reports, filed under seal.

³ E.g., Kolodny A. *How FDA Failures Contributed to the Opioid Crisis*. AMA J Ethics. 2020;22(8):E743-750. doi: 10.1001/amajethics.2020.743; Kolodny A, Frieden TF. *Government Actions to Curb the Opioid Epidemic-Reply*. JAMA. 2018 Apr 17;319(15):1620-1621; Kolodny A, Frieden TF. *Ten Steps the Federal Government Should Take Now to Reverse the Opioid Addiction Epidemic*. JAMA. 2017 Oct 24;318(16):1537-1538; Lin D, Lucas E, Murimi IB, Kolodny A, Alexander GC. *Potential Financial Conflicts of Interest and Federal Opioid Guidelines: A Cross Sectional Study*. JAMA Intern Med. 2017 Mar 1;177(3):427-428; Kolodny A, Courtwright DT, Hwang CS, Kreiner P, Eadie JL, Clark TW, Alexander GC. *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*. Annual Rev Public Health. 2015 Mar 18;36:559-74; Kolodny, A. "*Crooked Doctors Are Not Fueling the Opioid Epidemic*." New York Times. Feb 17, 2016; and Kolodny, A. "*Opioids Are Rarely the Answer*." New York Times. Feb 15, 2012.

of health, science, and governmental bodies, including the World Health Organization, the National Academy of Sciences, and the United States Senate Finance Committee. Notably, Dr. Kolodny's expertise arose organically and long before he was retained as an expert here or in any other matter. He started asking questions when he saw more and more patients with opioid addiction—and he has never stopped asking questions, exploring and researching the answers to those questions, and publishing his results. Doc. 1097-26 (Kolodny Rpt.) at 4-6.

In a case in which core questions include "who and what caused the flood of prescription opioids into our communities" and "what can be done to address the resulting devastation," a public health and policy expert like Dr. Kolodny is precisely what is needed to explain how the many parts come together.⁴ Public health is, by design, a multi-disciplinary approach that routinely looks beyond clinical issues to business and policy choices that impact public health outcomes. *Waite v. AII Acquisition Corp.*, 194 F. Supp. 3d 1298, 1310 (S.D. Fla. 2016) ("evaluation of the threats to human health and development of policies and practices to reduce those threats requires a thorough multidisciplinary evaluation of the available data.").

Unable to deny Dr. Kolodny's public health and policy expertise, Defendants seek to exclude portions of his testimony on five alleged grounds. As shown below, none of Defendants' objections come anywhere close to what is required to exclude an opinion under Rule 702. Even if there were any close calls, the Court can decide what weight to give the testimony.

Contrary to what Defendants argue, Dr. Kolodny is not offered to opine on any legal

⁴ Indeed, in its findings of fact after a comparable bench trial against various opioid manufacturers, an Oklahoma state court cited Dr. Kolodny's testimony in its ruling no less than thirty-six times. *See State of Oklahoma v. Purdue Pharma L.P.*, No. CJ-2017-816, 2019 WL 9241510 (Okl.Dist. Nov. 15, 2019). Defendants in that case brought a substantially similar motion to exclude, which the court rejected summarily.

standards. He opines on the recklessness of Defendants' conduct and on causation as a matter of *public health*, not law. There is no danger of "confusion" in a bench trial simply because the same concepts are relevant to both fields. *Infra* Section I.

Dr. Kolodny also is not offering any independent opinion about the legality of Defendants' suspicious order monitoring or their compliance with anti-diversion laws. Rather, as a public health expert examining how communities were flooded with prescription opioids, Dr. Kolodny looks to what others—the DEA, DOJ, U.S. GAO, other experts, and Defendants themselves—have concluded about Defendants' failures to keep these "controlled" substances under control. *Infra* Section III.

Defendants also claim Dr. Kolodny is opining on "credibility." But what Dr. Kolodny testified about was *conduct*—namely, Defendants' lies to Congress about their relationships with opioid manufacturers and their role in the Opioid Epidemic. If Defendants think Dr. Kolodny is wrong, they will cross-examine him. And if Dr. Kolodny is right, the Court will decide how the Defendants' lies affect their credibility. *Infra* Section V.

Dr. Kolodny also has more than ample basis to opine, from a public health perspective, on whether Defendants acted "prudently" given (a) the nature of the products, (b) notice that the products were being unlawfully marketed, and (c) awareness of the soaring statistics on opioid addiction, opioid use disorder, overdose, and death. Likewise, Dr. Kolodny does not need to be an expert on distribution or a lobbyist to opine on how Defendants helped wrongfully promote and supply prescription opioids and undercut efforts to curtail diversion. Dr. Kolodny is an expert on the origins and ongoing nature of the Opioid Epidemic. He properly examined Defendants' documents, data, testimony and conduct through that lens to explain how Defendants' actions were a substantial cause in creating and sustaining the Opioid Epidemic. *Infra* Sections II & IV.

Finally, Defendants fail to identify specific opinions they seek to exclude. Instead, they ask the Court to rule that five, ill-defined areas are off-limits. Def. Mem. at 11. For example, Defendants ask the Court to exclude unspecified opinions "based on" a "prudent distributor" standard or "related to" suspicious order monitoring or lobbying. Even if there were any substantive merit to Defendants' positions on these issues (there is not), the requested relief will only engender disputes and delay. Would Dr. Kolodny be prohibited from offering *any* criticism of Defendants' conduct? Would he be precluded from even *discussing* the DEA's penalties and citations of Defendants as part of his public health assessment of Defendants' role in the Opioid Epidemic? Defendants' requested relief sweeps too broadly and uncertainly and underscores that this motion is simply an effort to pre-view Defendants' cross-examination and not a well-founded request to exclude under Rule 702.

For all of the above reasons, and those set forth below, Plaintiffs respectfully request that the Court deny Defendants' Motion to Exclude the Expert Testimony in its entirety.

LEGAL STANDARD

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court provides an analytical framework for determining whether expert testimony is admissible under Rule 702 of the Federal Rules of Evidence. 509 U.S. 579 (1993). Federal Rule of Evidence 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Thus, pursuant to Federal Rule of Evidence 702, the district court functions as a gatekeeper, ensuring that the expert is qualified, and his or her testimony is both relevant and reliable. *Daubert*, 509 U.S. at 589, 590-91, 592-93; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149

(1999).

In Daubert, the Supreme Court identified four factors that a court may use in making its gatekeeping determination of reliability: (1) "whether a theory or technique. . . can be (and has been) tested," (2) "whether the theory or technique has been subjected to peer review and publication," (3) whether, "in the case of a particular scientific technique," there is a high "known or potential rate of error" and there are "standards controlling the technique's operation," and (4) whether the theory or technique enjoys "general acceptance" within a "relevant scientific community." 509 U.S. at 593-94. However, the *Daubert* factors are not definitive or exhaustive. See United States v. Crisp, 324 F.3d 261, 266 (4th Cir. 2003). ("Rather than providing a definitive or exhaustive list, *Daubert* merely illustrates the types of factors that will bear on the inquiry.") "[A]t bottom, the court's evaluation is always a flexible one, and the court's conclusions necessarily amount to an exercise of broad discretion guided by the overarching criteria of relevance and reliability." Belville v. Ford Motor Co., 919 F.3d 224, 233 (4th Cir. 2019), quoting Oglesby v. General Motors Corp., 190 F.3d 244, 250 (4th Cir. 1999). Thus, "the trial court has 'broad latitude' in determining whether *Daubert*'s specific factors are, or are not, reasonable measures of reliability in a particular case." Belville, 919 F.3d at 233; accord Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir.1999) ("In making its initial determination of whether proffered testimony is sufficiently reliable, the court has broad latitude to consider whatever factors bearing on validity that the court finds to be useful; the particular factors will depend upon the unique circumstances of the expert testimony involved.")

Moreover, as the Fourth Circuit has reminded, "[t]he trial court's role as a gatekeeper is not intended to serve as a replacement for the adversary system, and consequently, the rejection of expert testimony is the exception rather than the rule." *In re Lipitor (Atorvastatin Calcium) Mktg.*,

Sales Practices & Prod. Liab. Litig. (No II) MDL 2502, 892 F.3d 624, 631 (4th Cir. 2018). Indeed, Daubert itself stressed the importance of the "conventional devices" of "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" (rather than wholesale exclusion by the trial judge) as "the traditional and appropriate means of attacking shaky but admissible evidence." 509 U.S. at 596. "All Daubert demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable and helpful." Maryland Cas. Co. v. Therm-O-Disc, Inc., 137 F.3d 780, 783 (4th Cir. 1998). In evaluating whether the testimony is helpful, "[t]estimony from an expert is presumed to be helpful unless it concerns matters within the everyday knowledge and experience of a lay juror." Kopf v. Skyrm, 993 F.2d 374, 377 (4th Cir. 1993) (internal citations omitted).

The Supreme Court in *Daubert* was careful to emphasize that it is the expert's methodology, not her conclusion, that is the subject of the Rule 702 inquiry. Noting that the "overarching subject" of the Rule 702 inquiry "is the scientific validity and thus the evidentiary relevance and reliability of the principles that underlie a proposed submission," 509 U.S. at 594-95, the Court went on to hold:

The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.

Id. at 595. The Fourth Circuit has echoed this caution. See TFWS, Inc. v. Schaefer, 325 F.3d 234, 240 (4th Cir. 2003) (citing Freeman v. Case Corp., 118 F.3d 1011, 1016 n. 6 (4th Cir.1997)) see also Maryland Cas., 137 F.3d at 783 (plaintiffs "do not have to demonstrate to the judge . . . that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.")

Finally, as this Court has recognized numerous times, *Daubert* applies differently in a bench trial:

[T]he "better approach in this bench trial is to admit the testimony of all of the recognized experts that it permitted to testify and, in the words of the Supreme Court, allow vigorous cross-examination, presentation of contrary evidence and careful weighing of the burden of proof to test shaky but admissible evidence. Further, the court's concerns about the usefulness of various portions of the scientific testimony more appropriately can be addressed through determination of the weight to be accorded the testimony, rather than through the threshold determination of admissibility.

Grant Thornton LLP v. Fed. Deposit Ins. Corp., No. CIV.A. 1:00-0655, 2007 WL 4591412, at *1 (Faber, J.) (S.D.W. Va. May 6, 2007) (citation and internal quotation omitted); Grant Thornton, LLP v. F.D.I.C., No. CIV.A. 1:00-0655, 2004 WL 5524092, at *1 (S.D.W. Va. May 6, 2004) (same); Grant Thornton, LLP v. F.D.I.C., No. CIV.A. 1:00-0655, 2004 WL 6033093, at *1 (S.D.W. Va. May 6, 2004); see also Larosa v. Pecora, No. CIV.A. 1:07CV78, 2009 WL 3460101, at *3 (N.D.W. Va. Mar. 2, 2009) ("There is less need for the gatekeeper to keep the gate when the gatekeeper is keeping the gate only for himself." (citation and internal quotation omitted)).

ARGUMENT

I. PLAINTIFFS DO NOT OFFER DR. KOLODNY AS A LEGAL EXPERT

Dr. Kolodny uses his public health and Opioid Epidemic expertise to provide a powerful and detailed analysis of how Defendants' promotion and oversupply of opioids, and their failure to maintain meaningful protections against diversion, caused a public health crisis. In the face of this, Defendants recast Dr. Kolodny's testimony as being about law, not public health. Defendants are wrong. Just as a medical doctor can opine that a drug dealer's heroin was the cause of a victim's death in a criminal case (even though that testimony, if accepted by the finder of fact, would be outcome-determinative), *see U.S. v. Campbell*, 963 F.3d 309 (4th Cir. 2020), a public health expert like Dr. Kolodny can explain the cause of a public health crisis.

"Rule 704(a) allows the admission of expert testimony that 'embraces an ultimate issue to be decided by the trier of fact." U.S. v. McIver, 470 F.3d 550, 561 (4th Cir. 2006)(quoting Fed.

R. Evid. 704(a)). "In appropriate circumstances, an expert may offer an opinion that applies the facts to a legal standard." *Campbell*, 963 F.3d at 314. "[A]pplying medical expertise to form an opinion" on questions of causation is often the type of specialized knowledge that can help" a finder of fact. *Id*.

Fundamentally, Dr. Kolodny's testimony is about causation—that the Opioid Epidemic was "caused by overexposing the United States population, especially people in the State of West Virginia and the Cabell-Huntington Community, to prescription opioids," and that "[o]verexposure of the population to prescription opioids was a consequence of an enormous oversupply of prescription opioids by the pharmaceutical industry[.]" Kolodny Rpt. at 2. Causation is as much a public health concept as a legal one.

The mere fact that Dr. Kolodny opines on the unreasonableness of Defendants' conduct and its causal connection to the Opioid Epidemic as a matter of public health does not mean his opinions are excludable opinions on the law. This is not a case in which legal terms have "separate, distinct and specialized meaning in the law different from that present in the vernacular." *U.S. v. Perkins*, 470 F.3d 150, 158–60 (4th Cir. 2006). For this reason, Dr. Kolodny's opinions need not and should not be excluded as legal conclusions. *See Campbell*, 963 F.3d at 315 (allowing expert testimony because "[t]he commonly understood meaning of 'but for' and 'results from' do not diverge from their legal meaning."). If anything, Dr. Kolodny references legal standards in his report precisely to verify that his public health opinions on recklessness and causation "fit" the legal issues at hand, including the existence of a public nuisance.

That Dr. Kolodny's analysis speaks directly to the elements of a public nuisance and causation is not a basis to exclude his testimony. Experts routinely testify about such questions of fact, particularly in cases involving causation. *See Campbell*, 963 F.3d at 315 (collecting cases).

Such testimony is admissible precisely because it helps the jury make its ultimate findings. *Id.; see also McIver*, 470 F.3d at 562 n.14 ("This issue is a question of fact that is entrusted to the jury, and, therefore, is the proper subject of expert testimony.") (internal citations omitted).

Defendants also ignore that, even where applicable, the primary reason to exclude expert legal conclusions is to prevent "invad[ing] the judge's province of instructing the jury regarding the meaning of specialized legal terms." *U.S. v. Barile*, 286 F.3d 749, 760–61 (4th Cir. 2002); *see also U.S. v. Offill*, 666 F.3d 168, 175 (4th Cir. 2011)("Determining when legal conclusions would be helpful to the jury must also take into account the role that the judge has in instructing the jury on the law."). Because this is a bench trial, there is absolutely no danger that the Court would substitute Dr. Kolodny's understanding of the law for its own.

II. DR. KOLODNY HAS AMPLE EXPERTISE TO OPINE THAT THE DISTRIBUTORS FAILED TO ACT PRUDENTLY

Contrary to what Defendants argued (Def. Mem. at 6-7), Dr. Kolodny's opinions on whether the Defendants acted prudently—with reasonable concern for the health consequences of their actions and inaction—fall squarely within his areas of expertise—public health and the origins, nature, and consequences of the Opioid Epidemic—and are well specified and supported.

Defendants argue that whether they acted prudently is not a proper subject of expert testimony because Dr. Kolodny testified that "I don't think you need to take a class or go to -- or earn a degree on what a prudent distributor of narcotics should do." *See* Def. Mem. at 6. But expertise does not only arise merely from classroom study; experts may qualify on the basis of their experience as well as their education. *See* Fed. R. Evid. 702 ("a witness who is qualified as an expert by knowledge, skill, experience, training, *or* education. . . .") (emphasis added); *see also Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 191 (4th Cir. 2014) (expert with substantial professional experience in bicycle accidents had reliable foundation for testimony based on his

experience); *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012) (in determining whether expert has sufficient specialized knowledge to make his or her testimony helpful, court should "consider the proposed expert's full range of experience and training, not just his professional qualifications). The behavior of those registered and authorized to distribute narcotics is not a topic within the everyday knowledge and experience of laypersons. *See Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993) ("[t]estimony from an expert is presumed to be helpful unless it concerns matters within the everyday knowledge and experience of a lay juror.") (internal citations omitted).

Here, Dr. Kolodny's expertise about the Opioid Epidemic does not arise merely from academic credentials. He also has enormous professional experience investigating and responding to the epidemic as a public health official and policy advocate, which fundamentally includes understanding what conduct is prudent *from a public health perspective* for *any* actor involved in the Opioid Epidemic. That Dr. Kolodny did not form this particular expertise in a classroom is not a basis to exclude his testimony.

Nor are Defendants correct that Dr. Kolodny's opinions in this area are unreliable because they are based on his observations. *See* Def. Mem. at 7. As the Supreme Court has explained, "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience." *Kumho Tire*, 526 U.S. at 156; *see also Eskridge*, 556 F. App'x at 190-1 (bicycle expert's "involvement with hundreds of cases of accidents involving quick-release systems and his decades of experience in the industry in general certainly provided him with a strong foundation for testifying regarding those facts."). Dr. Kolodny has more than a decade of personal, academic, and professional knowledge of the acute dangers of massive oversupply of opioids and of the role that misleading promotion as well as the failures to monitor and control the

supply chain have had in building and sustaining the epidemic. Kolodny Rpt. at 4-5. Defendants' insistence on an "industry standard" (Def. Mem. at 7) misses the point entirely. This is not a contract dispute about whether Defendants reasonably carried out their obligations as distributors. This is a case about a public health crisis and Dr. Kolodny has ample basis to opine on what was and was not prudent, from a public health perspective, for Defendants to do when selling and distributing narcotics generally—and in the face of the growing epidemic.

Defendants also complain Dr. Kolodny allegedly does not articulate what prudent distributors should have done. Def. Mem. at 6-7. Defendants are wrong. Dr. Kolodny is specific and concrete. "Prudent distributors of narcotics drugs would not have participated in a campaign to increase the supply of opioids[.]" Kolodny Rep. at 105 (emphasis added). "Prudent distributors of narcotics would not have repeatedly shipped narcotics to corrupt pharmacies" and instead "would have maintained robust systems to detect diversion[.]" Id. "Prudent distributors of narcotics would not have participated in a campaign to deceive policymakers and the public about the adequacy of their monitoring systems[.]" Id. These standards are clear, objective, and firmly rooted in Dr. Kolodny's public health expertise.

Finally, Defendants' suggestion that because Dr. Kolodny's opinions are personally held they cannot be expert opinions (Def. Mem. at 7) is flatly contradicted by Fourth Circuit precedent. "That [an expert's] opinion was a personal opinion does not somehow mean it was not a professional one." *Eskridge*, 556 F. App'x 182, 190 (4th Cir. 2014). Defendants' complaint that Dr. Kolodny opines on facts learned in the course of this litigation is similarly groundless. The fact that it took this lawsuit to allow Dr. Kolodny to see in detail the complete picture of the distributors' role in the Opioid Epidemic in which he has been immersed for so long is not a basis to exclude his opinions. What is helpful to the trier of fact is to have an expert, like Dr. Kolodny,

analyze and explain, from his years of experience, the significance of the facts now being disclosed. *See* Pltfs. Opp. to Mtn to Exclude Opinions on Corporate Conduct, at 4-7 (discussing cases approving experts' synthesis of facts developed in discovery).

III. DR. KOLODNY DOES NOT OPINE ON WHETHER DEFENDANTS MET THEIR LEGAL OBLIGATIONS FOR SUSPICIOUS ORDER MONITORING

Contrary to what Defendants argue (Def. Mem. at 7-8), Plaintiffs are not offering Dr. Kolodny as an expert on the anti-diversion laws or regulations applicable to Defendants, nor to opine on whether Defendants complied with their obligations under the Controlled Substances Act. However, as a public health expert examining the recklessness of Defendants' conduct and the causes of the Opioid Epidemic, he can and should take into account whether and how Defendants complied with their legal obligations to monitor for and prevent diversion of prescription opioids, as well as the excuses Defendants have offered for why they did not comply with those obligations.

Dr. Kolodny does this by relying on what others have found and said about Defendants' compliance. For example, he cites the findings and observations of the DEA, a Congressional committee, the Department of Justice, and the U.S. GAO about Defendants' years of unbridled shipments of opioids and failure to prevent evident diversion—as well as DEA fines and citations for Defendants' violations of anti-diversion requirements. Kolodny Rpt. at 52, 60-61, 64. Dr. Kolodny further relies on analyses done by others concerning the patterns of "red flags" of suspicious orders Defendants ignored and how the limited suspicious monitoring efforts the defendants made systematically failed.⁵ Dr. Kolodny also relies on what Defendants themselves said about their anti-diversion efforts—including ways to help customers structure orders so as to

⁵ Dr. Kolodny cites the reports of James Rafalski, Craig McCann, and Lacey Keller throughout his discussion of Defendants' failure to prevent diversion. Kolodny Rpt. at 51-65.

evade their own suspicious order monitoring systems.⁶ These sources provide a reliable foundation for Dr. Kolodny's opinions about the appropriateness of Defendants' conduct from a public health perspective.

Dr. Kolodny does not need to be an expert on the Controlled Substances Act or suspicious order monitoring algorithms to opine that—in light of what law enforcement, other experts, and Defendants' themselves have found—Defendants acted recklessly and unreasonably and that their actions were "a substantial factor in creating the Opioid Epidemic in the Cabell Huntington Community." Kolodny Rpt. at 63. As an expert with years of experience studying and responding to the Opioid Epidemic, Dr. Kolodny has more than sufficient understanding that the Controlled Substances Act and suspicious order monitoring regulations were intended to prevent exactly the devastating public health consequences at issue here. *See*, *e.g.*, Exh. A (excerpts from Dr. Kolodny's deposition in the Ohio AG action) at 80:12-81:19, 82:2-12, 83:9-84:24.

IV. DR. KOLODNY PROPERLY EXAMINES THE ROLE OF DEFENDANTS' FRONT GROUPS AND LOBBYING IN NORMALIZING PRESCRIPTION OPIOID USE AND UNDERCUTTING EFFORTS TO CONTROL THE EPIDEMIC

Defendants also seek to preclude Dr. Kolodny from testifying to Defendants' use of industry-funded front groups and lobbying as a key factor in creating and sustaining the Opioid Epidemic. Def. Mem. at 8-10. Defendants' argument rests on basic mischaracterizations of Dr. Kolodny's expertise.

First, as detailed above and in his report, Dr. Kolodny is not only "an addiction treatment doctor." Def. Mem. at 9. In the early 2000s, he led one of the nation's first public health efforts to address the Opioid Epidemic as a medical director in the New York City Department of Health

⁶ E.g., Kolodny Rpt. at 62-65.

⁷ Dr. Kolodny himself is a DEA registrant subject to the Controlled Substances Act and accompanying regulations. Exh. A at 81:3-19.

and Mental Hygiene. Def. Exh. 2 at 4. He then went on to research how industry-funded initiatives were impacting opioid prescribing and the relationships between the industry and ostensibly independent "pain organizations" (*id.* at 5)—exactly the areas that Defendants wrongly claim Dr. Kolodny examined only in the context of litigation.

As Dr. Kolodny explains, his research and consulting on the causes of and potential solutions to the Opioid Epidemic require him to understand these dynamics and relationships. *Id.* His knowledge and experience informs not only the opinions he offers here, but the work he does with numerous stakeholders, including the World Health Organization, the National Governors Association, the National Judicial Opioid Task Force, and the National Academy of Science. *Id.* As a result, Dr. Kolodny is well versed in the industry's use of "front groups" and lobbying and their impact on the course of the Opioid Epidemic. *Id.*

In short, Dr. Kolodny's seventeen years of work on the Opioid Epidemic as a clinician, public health official, researcher, and advocate provide more than sufficient "specialized expertise" for his opinions on Defendants' use of front groups and lobbying. Defendants' claim that Dr. Kolodny is just "reading documents" and "offering his personal viewpoints" thus rings hollow. One of the fundamental purposes of the *Daubert* inquiry is to ensure that an expert uses the same rigor in the courtroom as is used in the field. *See Kumho Tire*, 526 U.S. at 152. Here, Dr. Kolodny's opinions align precisely with his work in the field. As set forth in Plaintiffs' Opposition to Defendants' Motion to Exclude Opinions on Corporate Conduct (at 4-8), it is entirely proper for an expert such as Dr. Kolodny to review and synthesize documents, data, and testimony in order to bring his expertise to bear on the particular facts in the case and explain their significant to his expert opinions.

V. DR. KOLODNY DOES NOT OFFER OPINIONS ON "CREDIBILITY"

Defendants' claim that Dr. Kolodny is opining on "credibility" (Def. Mem. at 10) is

meritless. The only "credibility" opinions Defendants cite are from Dr. Kolodny's deposition, not his report, and were offered only in response to questions pressed by counsel for McKesson. When asked why he did not trust McKesson's statements, Dr. Kolodny pointed to McKesson's lying. Def. Ex. 2 (Kolodny Dep. Tr., 181:4-183:15). *In response to a specific question from counsel for McKesson* about why Dr. Kolodny did not trust McKesson's representations about its suspicious order monitoring programs, Dr. Kolodny explained that McKesson's CEO falsely told Congress that McKesson had only a "logistics" role in supplying prescription opioids—and said nothing of McKesson's broader role in helping prescription opioid manufacturers with promotions, education, and patient adherence (among other things). *Id*.

McKesson no doubt is stinging from Dr. Kolodny's astute observation that the facts uncovered in discovery here put the lie to what McKesson told Congress. But a witness—including an expert—is entitled to testify to specific, relevant acts of lying. Such testimony about actual *conduct* is permitted—and it is for the trier of fact to determine whether McKesson did lie to Congress and, if so, what the broader implications are for McKesson's credibility. Nor is it proper for Defendants to elicit, at deposition, testimony not offered by an expert in his report, only to seek to exclude the testimony they themselves brought forth.

VI. DEFENDANTS FAIL TO IDENTIFY ANY SPECIFIC OPINIONS TO EXCLUDE

For all of the foregoing reasons, Defendants' attacks on Dr. Kolodny's opinions are meritless. Even if Defendants raised any valid argument, however, Defendants' motion also fails because it does not identify with specificity which of Dr. Kolodny's opinions should be excluded. Defendants claim they do not seek to exclude all of Dr. Kolodny's opinion. Yet, Defendants only gesture to general categories they contend are improper without rooting those categorizations in specific sections of Dr. Kolodny's 114-page report.

Motions in limine to exclude "broad categor[ies] of information" are improper because "the Court cannot rule in a vacuum." In re Cathode Ray Tube (CRT) Antitrust Litig., 2016 WL 7803893, at *2 (N.D. Cal. Nov. 15, 2016). This is particularly true for motions to exclude expert opinions. Without "the specific content and nature of the opinions and testimony" at issue, the court cannot reasonably be asked to determine which opinions, if any, are excludable and which are not. AMX Corp. v. Pilote Films, 2007 WL 2428940, at *2 (N.D. Tex. Aug. 27, 2007). See also Mabrey v. Wizard Fisheries, Inc., 2007 WL 1876540, at *1 (W.D. Wash. June 27, 2007) ("Without offering a specific opinion to be excluded under this rule, the Court cannot preemptively grant defendant's motion in limine.") and In re Ethicon, Inc., 2016 WL 4473449, at *3 (S.D.W. Va. Aug. 24, 2016)("Nor can I assess the plaintiffs' general reliability concerns without more detail as to the testimony they wish to exclude.).

The practical problems with overly generalized motions to exclude are clear. Such motions either create serious problems in trial administration—because the parties are forced to endlessly dispute which questions fall within the scope of the court's prior ruling and which do not—or they put the Court in the position of having to comb through a complex expert report to identify what opinions are excludable and which are not—despite the fact that burden lies with the movant. Neither of these options are appropriate.

Defendants have exacerbated this problem by phrasing their actual requests for relief in remarkably vague ways. Defendants ask that Dr. Kolodny be excluded from testifying about opinions "based on a 'prudent distributor' standard" or "related to suspicious order monitoring or regulatory compliance[.]" Def. Br. at 11. What would granting those requests mean? Would Dr. Kolodny be prohibited from offering *any* criticism of Defendants' conduct, just because the defendants are distributors? Would he be precluded from even *discussing* the DEA's penalties

and citations of Defendants as part of his public health assessment of Defendants' role in the Opioid Epidemic? The answers are unclear because Defendants have chosen to frame their motion in vague and general terms, rather than specifying what testimony they want to exclude.

Defendants' failure to sufficiently specify which opinions they ask the Court to exclude provides an additional, independent basis to deny the motion.

CONCLUSION

For the foregoing reasons, this Court should deny in its entirety Defendants' Motion to Exclude the Expert Testimony of Andrew Kolodny.

Dated: October 23, 2020 Respectfully submitted,

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I certify that on October 23, 2020, a copy of the foregoing was filed

electronically. Notice of this filing will be sent to all parties by operation of the Court's

electronic filing system. Parties may access this filing through the Court's system.

This filing will also be served on all parties by email to:

 $Track 2 Opioid Defendants@Reed Smith.com\ and\ CT2_Opioid_Team@mail-list.com.$

/s/ Anthony J. Majestro